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MORGAN, LEWIS & BOCKIUS LLP			CUMBERLEDGE, JERRY L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/749,345	VAUGHEN ET AL.
	Examiner	Art Unit
	Jerry Cumberledge	3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 April 2007.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-63 is/are pending in the application.
 4a) Of the above claim(s) 9-12,26-29,34 and 46-51 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-8,13-25,30-33,35-45 and 52-63 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 30 December 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>04/25/2006; 02/17/2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, Species A (claims 1-8, 13-25, 30-33, 35-45 and 52-63) in the reply filed on 04/27/2007 is acknowledged.

Claims 9-12, 26-29, 34 and 46-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method and nonelected species of Group I, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/27/2007.

Claim Objections

Claim 22 is objected to because of the following informalities: It appears that the word "an" is missing between "has" and "inside". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "four of said fastening plates" and "four links" in line 2. There is insufficient antecedent basis for this limitation in the claim. The claims

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upon which claim 15 is dependent require a plurality of plates, but do not require there to be four plates.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8, 14, 15, 17-21, 24, 30, 33, 35-38, 41-45 and 52-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Duncan (US Pat. 5,766,176).

Duncan discloses a resorbable contourable fixation device comprising: a plurality of spaced-apart fastening plates (Fig. 7, ref. 32); and a plurality of deformable links (Fig. 7, ref. 34) interconnecting said fastening plates; wherein said fastening plates and said links are made of a resorbable material (column 4, lines 32-38), said fixation device being contourable in three-dimensions (column 1, lines 5-8). The resorbable device comprises a plurality of elongate openings (Fig. 7, near where refs. 76 are written) interspersed between said fastening plates (Fig. 7). The links have a smoothly curved arcuate shape (column 6, lines 26-38). The fastening plates do not deform when said fixation device is contoured. The fixation device is formed from a monolithic single sheet of material (Fig. 7). The resorbable fixation device further comprises at least some of said fastening plates having holes (Fig. 7, ref. holes through refs. 32) therethrough to receive a fastener for securing said fixation device to the bone. The fastening plates are

generally round in shape (Fig. 10)(column 4, lines 53-56). A portion of the periphery of four of said fastening plates and a portion of the periphery of four links forms elongate openings (Fig. 7, near where refs. 76 are written) in said fixation device. The elongate openings before contouring are symmetrical in shape (Fig. 7). At least some of said elongate openings after contouring in at least two planes are not symmetrical in shape. At least some of said links contact each other or the fastening plates after contouring, thereby increasing the rigidity of said fixation device, since the links still contact the plates after contouring (Fig. 8A). The resorbable device comprises each of said links having a first end connectable to one of said fastening plates and a second end connectable to a different said fastening plate, since each link is connected to two different fastening plates (Fig. 7). The links are connected to said fastening plates such that said links extend radially outwards from said fastening plates in a spiral pattern (Fig. 7). The links having a concave side (column 6, lines 26-38). The fixation device has a substantially square shape (column 7, lines 34-38). The resorbable fixation device further comprises at least two rows of spaced-apart fastening plates, each of said rows including at least two fastening plates (Fig. 7).

Duncan discloses a resorbable fixation device capable of being secured to bone, said fixation device comprising: a plurality of spaced-apart fastening plates (Fig. 7, ref. 32), at least some of said fastening plates having a fastener hole (Fig. 7, ref. 32) therethrough to receive a fastener for securing said fixation device to the bone; a plurality of arcuately-shaped (column 6, lines 26-38) links (Fig. 7, ref. 34) interconnecting said fastening plates and extending from said fastening plates in a spiral

pattern (Fig. 7); wherein said fastening plates and links are made of a resorbable material (column 4, lines 32-38), wherein a plurality of said fastening plates are interconnected by four links (Fig. 7), said interconnected fastening plates and links form an open-structured deformable fixation device having elongate openings (Fig. 7, near where ref. numerals 74 are written) therein, said fixation device capable of being contoured in three dimensions (Fig. 8A)(column 1, lines 5-8). The fixation device further comprises at least four fastening plates (Fig. 7), said plates arranged in at least two rows of at least two fastening plates in each row (Fig. 7, rows going from top to bottom of page), said rows arranged in spaced-apart relationship to each other (Fig. 7).

Duncan discloses a resorbable contourable fixation device comprising: at least two rows of spaced-apart fastening plates (Fig. 7, ref. 32), each of said rows including at least two fastening plates (Fig. 7); at least one arcuately-shaped (column 6, lines 26-38) link (Fig. 7, ref. 34) interconnecting each of said fastening plates to at least one other fastening plate (Fig. 7); said fastening plates and links arranged to define a plurality of elongate-shaped openings in said fixation device; wherein said fastening plates and said links are formed of a resorbable material, and whereby said fastening plates, links, and elongate openings (Fig. 7, near where ref. numerals 74 are written) define an open-structured fixation device capable of being contoured in three dimensions (Fig. 8A). At least some of the elongate openings are oriented vertically and at least some of said elongate openings are oriented horizontally with respect to said fixation device (Fig. 7). The links radiate outward from said fastening plates in a spiral pattern (Fig. 7, near ref. 32, center).

Duncan discloses a resorbable contourable fixation device formed from a plurality of repeating base fixation device units (Fig. 7), each said base fixation device unit comprising: four spaced-apart fastening plates (Fig. 7, four refs. 32), said fastening plates arranged such that each said fastening plate forms a corner of said base fixation device unit (column 7, lines 34-38, since the square form will have four corners), at least some of said fastening plates having a hole (Fig. 7, holes through refs. 32) passing therethrough to receive a fastener for attaching said base fixation device unit to a bone; at least four arcuately-curved (column 6, lines 26-38) links (Fig. 7, ref. 34) connecting said fastening plates together (Fig. 7), said at least four links arranged around an opening (Fig. 7, near where ref. numerals 74 are written) formed by said at least four links and at least a portion of said fastening plates; wherein said base fixation device is made from a resorbable material (column 4, lines 32-38) having a glass transition temperature (Tg); whereby said base fixation device unit is changeable between: a first condition wherein the temperature of said base fixation device unit is below the glass transition temperature (Tg) and said base fixation device unit is substantially rigid, and b) a second condition wherein the temperature of said base fixation device unit is above the glass transition temperature (Tg) (column 4, lines 32-38) and said base fixation device unit is flexible and contourable in three dimensions. In regard to the glass transition temperature, it is noted that Duncan teaches using polymers (column 4, lines 32-38), which have a glass transition temperature. The resorbable fixation device comprises said fastening plates being substantially round in shape (as in Fig. 10). The fastening plates are equally spaced apart so as to form a substantially square shape

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(column 7, lines 34-38,e.g. square shape). Two of said at least four arcuately-curved links project inwards toward said opening and two of said at least four arcuately-curved links project outwards from said opening (Fig. 7, near ref. 32 center). The opening is substantially elongate and symmetrical in shape (Fig. 7).

Duncan discloses a resorbable contourable fixation device kit comprising: at least a first resorbable (column 4, lines 32-38) fixation device comprising: a plurality of spaced-apart fastening plates (Fig. 7, refs. 32); a plurality of deformable links (Fig. 7, ref. 34) interconnecting said fastening plates; a plurality of elongate openings (Fig. 7, near where ref. numerals 74 are written) interspersed between said fastening plates, wherein said fastening plates and said links are made of a resorbable material (column 4, lines 32-38), said fixation device being contourable in three-dimensions (e.g. Fig. 8A); and a plurality of fasteners (column 4, lines 39-48) for attaching said fixation device to bone. The links have a curved arcuate shape (column 6, lines 26-38). The links extend radially outward from said fastening plates in a spiral pattern (Fig. 7, near ref. 32, center). At least some of said fastening plates have a fastener hole (Fig. 7, holes through refs. 32) therethrough. At least some of said fasteners are made from a resorbable material (column 4, lines 32-38). The fasteners include screws (column 4, lines 39-48) or tacks. At least first fixation device has a shape selected from the group consisting of square (column 7, lines 34-38,e.g. square shape), round, and crescent. The kit further comprises at least a second resorbable fixation device, said second fixation device having a different overall size than said at least first fixation device (column 9, lines 39-41, since the surgeon selects the appropriate size mesh). The kit

further comprises at least a second resorbable fixation device, said second fixation device having

With regard to claim 7, it is noted that the device of Duncan appears to be substantially identical to the device claimed, although possibly produced by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983).

With regard to statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the device/kit of Duncan, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 13, 16, 22, 23, 25 and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan (US Pat. 5,766,176).

Duncan discloses the claimed invention except for the fastener holes being spaced at a distance of about 5 mm from each other measured from center to center of said fastener holes; the connection between said concave side of said links and said fastening plates has an inside radius of about 0.6 mm; and the arcuate links having a width of about 0.8 mm, an inside radius of curvature of about 2.2 mm and an outside radius of curvature of about 3 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the device of Duncan with the fastener holes being spaced at a distance of about 5 mm from each other measured from center to center of said fastener holes; the connection between said concave side of said links and said fastening plates having an inside radius of about 0.6 mm; and the arcuate links having a width of about 0.8 mm, an inside radius of curvature of about 2.2 mm and an outside radius of curvature of about 3 mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Duncan discloses the claimed invention except for the elongate openings having a length of about 7.0 mm to about 8.0 mm and a minimum width of about 1.0 mm to about 1.5 mm.; the fixation device having a thickness of about 0.25 mm to about 1.2 mm; and the fixation device being about 20 mm x 20 mm square to about 150 mm x 150 mm square. It would have been obvious to one having ordinary skill in the art at the time

the invention was made to have constructed the device of Duncan with the elongate openings having a length of about 7.0 mm to about 8.0 mm and a minimum width of about 1.0 mm to about 1.5 mm.; the fixation device having a thickness of about 0.25 mm to about 1.2 mm; and the fixation device being about 20 mm x 20 mm square to about 150 mm x 150 mm square, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Duncan discloses the claimed invention except for the second fixation device being a different shape than said at least first fixation device; the second fixation device having a different thickness than said at least first fixation device; the kit further comprises at least a third resorbable fixation device, said third fixation device having a different shape than said at least first and second fixation devices.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the kit of Duncan with a third fixation device, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

It would have been an obvious matter of design choice to have constructed the second fixation device of Duncan with a different thickness than the first fixation device, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to have constructed the first, second and third fixation devices of Duncan with differing shapes, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of fixing a bone. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 31, 32, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan (US Pat. 5,766,176) in view of Barrows (US Pat. 5,013,315).

Duncan discloses the claimed invention except for the resorbable material contains lactide and the resorbable fixation device further comprises glycolide.

Barrows discloses a device for use in bone fracture fixation (abstract) which contains a resorbable material (abstract) that comprises lactide and glycolide (column 5, lines 34-50). These materials are used because they are well known to be tolerated by the body upon implantation in addition to being absorbable (column 5, lines 46-50).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Duncan with the resorbable material comprising lactide and glycolide as taught by Barrows, since these materials are well tolerated by the body upon implantation in addition to being absorbable (column 5, lines 46-50).

Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan (US Pat. 5,766,176) in view of McKay et al. (US Pub. 2001/0001129 A1).

Duncan discloses the claimed invention except for the resorbable material being radiolucent.

McKay discloses a resorbable (paragraph 0092) fusion device (paragraph 0002) that is comprised of a radiolucent material (paragraphs 0009 and 0010) in order to provide for visualization of the fusion mass (paragraph 0010).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Duncan with radiolucent material as taught by McKay, in order to provide for visualization of the fusion mass (paragraph 0010).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC

JCC

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SUPERVISORY PATENT EXAMINER